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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Arieh Sher

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44696

7590

02/18/2009

DR. MARK M. FRIEDMAN

C/O BILL POLKINGHORN - DISCOVERY DISPATCH

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EXAMINER

LAMPRECHT, JOEL

ART UNIT

PAPER NUMBER

3737

NOTIFICATION DATE

DELIVERY MODE

02/18/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/531,184	Applicant(s) SHER, ARIEH	
	Examiner JOEL M. LAMPRECHT	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/19/08 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13, 16-25, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al (US 2002/0077642 A1) in view of McKenzie et al (5,993,469). Patel et al discloses a method of atherectomy including the use of an imaging guidewire passing through a central lumen of a catheter for the purpose of facilitating imaging of a target site and subsequent plaque removal by a working head coupled with an actuator (Fig 2-8, 0064-0070). The device and methods include a positioning element for positioning of the catheter in the lumen (0084), a rotatable cutting edge (Figure 20), input devices controlled by automatic

on/off control (0080-0084, 0013) and driver shaft control of the rotation speed of the removal device (0082).

Patel et al do not disclose the use of CPU controlled operation of the working head element or balloon placement (though an alternative positioning element is used). Attention is directed to the previously mentioned reference to McKenzie et al which teaches a method and apparatus for reducing restriction of blood flow in a lumen of a blood vessel comprising inserting imaging system into the lumen capable of generating cross-sectional images of the lumen (Col 9 Line 35-50, Col 11 Line 65-Col 12 Line 65, Col 18 Line 30-45), propelling a catheter including a "working head" with imaging system to the plaque (Col 11 Line 16-65), scanning the lumen with the imaging system to image the lumen (Col 11 Line 65-Col 12 Line 65), positioning the catheter in the lumen using a position element and monitoring the image to determine if the head is positioned in a desired location (Col 18 Line 5-45), and finally operating the working head to remove the intraluminal plaque (Col 19 Line 10-Col 20 Line 5). The working head disclosed by McKenzie et al contains a cutting edge which is operative when rotated and is capable of operation prior to traverse of the plaque (Col 16 Line 35-60), positioning elements include a number of balloons which can circumferentially surround the catheter (Col 18 Line 5-45), contains a control system which can aid in positioning, scanning, inserting, monitoring (Col 12 Line 35-Col 13 Line 17, Col 19 Line 10-30), and operating the device and can be operated by inputs from the operator, a removal device including for removal of the plaque (Col 17 Line 50-Col 18 Line 3), a therapeutic lumen and a central

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vacuum lumen for removal of the plaque removed by the cutting device (Col 12 Line 10-35). It would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated the system and methods of Patel et al with the system of McKenzie for the purpose of allowing for a flexible plaque removal method which allows for real-time monitoring of the target site before advancement of a working element to the target.

Claims 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel in view of McKenzie as applied to claim 16 above and in further view of Findlay et al (US 6,623,495 B2). Patel et al in view of McKenzie disclose all that is listed above, but fail to mention the use of an “Archimedes Screw” incorporated into the design to facilitate removal of a portion of the plaque or a central vacuum lumen. Attention is then directed to the teaching reference by Findlay et al which discloses the use of an Archimedes screw and vacuum suction lumen in the same area of endeavor in conjunction with a guidewire for the purpose of plaque removal (Col 5 Line 51-Col 6 Line 25). It would have been obvious to one of ordinary skill in the art to have used the Archimedes screw functionality of Findlay et al with the imaging guidewire plaque removal system of Patel in view of McKenzie et al for the distinct purpose of improving plaque removal after and during a cutting procedure within the vessel.

Claims 14, 15, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel in view of McKenzie as applied to claims 1 and 16

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above, and further in view of Masch (US 4,728,319). Patel in view of McKenzie et al discloses all that is listed above but fail to include specifics on the rotational speeds of the cutting head. As the listed RPMs within the current applications are outside of the norms for traditional cutting with a high speed head attention will be directed to the secondary reference by Masch that describes the use of a cutting element with a screw-like design which is used at 10-60 RPM for the removal of plaque elements within the body (Fig 1-5, Col 6 Line 20-55). It would have been obvious to one of normal skill in the art at the time of the invention to have enhanced the teachings of Patel in view of McKenzie et al with those of Masch et al to provide a low-speed cutting element for removal of plaque within arteries of the body.

Claims 14, 15, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel in view of McKenzie as applied to claims 1 and 16 above, and further in view of Chornenky et al (US 5,582,171). Patel in view of McKenzie do not disclose the use of a folding mirror at the distal tip of the imaging guidewire. Attention is then directed to the teaching reference to Chornenky et al which discloses the use of a moveable mirror at the distal tip of an imaging guidewire for assistance in placement of an IV catheter (Col 2 Line 15-Col 3 Line 25). It would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated a rotatable, movable mirror of Chornenky in the system and methods of Patel in view of McKenzie as the mirror allows for further adaptive imaging of the lumen of a target site.

Response to Arguments

Applicant's arguments with respect to claims 1-31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL M. LAMPRECHT whose telephone number is (571)272-3250. The examiner can normally be reached on 8:30-5:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/BRIAN CASLER/
Supervisory Patent Examiner, Art
Unit 3737

JML